

REMARKS

Currently Claims 1-64 are pending. Claim 1 has been canceled without prejudice. Claim 2 has been amended to place it in independent form. Claims 8, 10, 11, 13, 15-25, and 58 have been amended to depend from claim 2. Applicants address below each of the rejections presented in the Office Action.

I. 102(b) Rejections

Claims 2, 4-10, 13, 14, 21-23, 25-27, 29-40, 42, 43, 47-49, 56 and 58 have been rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/41254 (“Bacon”). Applicant respectfully traverses these rejections.

Claim 2 recites a system for delivering a pharmaceutical formulation to a patient that includes:

- a container having a pharmaceutical formulation comprising at least one medicament present therein;

- a metering assembly in communication with said container;

- a tubular nozzle having an inlet configured in size to communicate with the metering assembly, and an outlet for directing the medicament to a patient, wherein the tubular nozzle has at least one curved portion;

- wherein the tubular nozzle has a defined length and a longitudinal axis that is curvilinear throughout the defined length of the tubular nozzle, the tubular nozzle having a radius of curvature of at least 2.5 times the inner diameter of the tubular nozzle present within the curved portion, wherein the tubular nozzle includes at least one tapered section.

As described in Applicant’s specification at page 8, a “tapered section” is defined as a length of the tubular nozzle over which the diameter changes, connecting the diameters at each end of the tapered portion via a smooth fluid flow path. The tapered section represents the diameter transitions within the tubular nozzle, and are designed to maintain a smooth fluid flow path. The tapered section provides a smooth reduction or increase in diameter with no sharp edges or corners.

The Office Action asserts at page 3 that Bacon teaches an apparatus wherein the tubular nozzle includes at least one tapered section. In support of this assertion,

the Office Action cites Figure 2 and draws attention to the section left of reference character 14. The Office Action states that this section is “defined as tapered.” However, Applicant has found no language in the specification of Bacon that would define this section as being tapered. Instead, page 8, lines 24-28, state that “When the piston is in this position, the tube has straightened sufficiently to release the obturation at the kinks, so that the dose can flow through the throughbore 16 which has a mouth 27 shaped for aerosol dispersion.” Thus, Figure 2 merely illustrates a flexible tube that is partially unkinked at positions 13 and 14 to allow flow through it.

Positions 13 and 14 of Bacon are not “tapered sections” as defined in Applicant’s specification and recited in claim 2. Positions 13 and 14 are not lengths of the tubular nozzle over which the diameter changes, connecting the diameters at each end of the tapered portion via a smooth fluid flow path. Positions 13 and 14 are not designed to maintain a smooth fluid flow path. Positions 13 and 14 do not provide a smooth reduction or increase in diameter with no sharp edges or corners. In fact, positions 13 and 14 of Bacon are merely partially unkinked segments of a flexible tube. As one can clearly see in Figure 2, partially unkinked positions 13 and 14 do have sharp edges or corners.

For at least the foregoing reasons, Claim 2 is not anticipated by Bacon. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claims 4-10, 13, 14, 21-23, 25-27, 29-40, 42, 43, 47-49, 56 and 58 each depend from patentable independent claim 2. For at least this reason and without acquiescing in the Action’s rejections of these claims, Applicant respectfully submits that these dependent claims are also patentable and requests that these rejections be withdrawn. Should the Examiner decide not to issue a Notice of Allowance in response to this Amendment, Applicant expressly reserves the right to argue the separate patentability of one or more of these dependent claims.

II. 103 Rejections

Claims 3, 11, 12, 24, 28, 41, 44-46 and 57 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bacon. Applicant respectfully traverses these rejections.

Claims 3, 11, 12, 24, 28, 41, 44-46 and 57 each depend from patentable independent claim 2. For at least this reason and without acquiescing in the Action's rejections of these claims, Applicant respectfully submits that these dependent claims are also patentable and requests that these rejections be withdrawn. Should the Examiner decide not to issue a Notice of Allowance in response to this Amendment, Applicant expressly reserves the right to argue the separate patentability of one or more of these dependent claims.

Claims 15-20, 50-55 and 59-64 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bacon in view of U.S. Patent No. 6,360,739 to Rand. Applicant respectfully traverses these rejections.

Claims 15-20, 50-55 and 59-64 each depend from patentable independent claim 2. For at least this reason and without acquiescing in the Action's rejections of these claims, Applicant respectfully submits that these dependent claims are also patentable and requests that these rejections be withdrawn. Should the Examiner decide not to issue a Notice of Allowance in response to this Amendment, Applicant expressly reserves the right to argue the separate patentability of one or more of these dependent claims.

III. Conclusion

Applicant respectfully submits that the present application is in condition for allowance and requests the issuance of a Notice of Allowance forthwith. Should the Examiner have any questions relating to this application, Applicant encourages the Examiner to contact Applicant's representative, who can be reached by telephone at (919) 483-9024.

Date: <u>January 8, 2008</u> GlaxoSmithKline Corporate Intellectual Property Five Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709 Tel. (919) 483-9024 Fax: (919) 483-7988
--

Respectfully submitted:

//J. Michael Strickland //

J. Michael Strickland
Attorney for Applicants
Reg. No. 47,115